PhUSE 2007

Paper PO14

A "Systematic Review" of PhUSE
What PhUSE users made available to the public after two years

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ABSTRACT

So far PhUSE has been an exciting initiative. European Pharmaceutical Software Users now have a place where they can present and share their experience.

In the first two PhUSE conferences (2005 and 2006) and in the current one (2007), 273 papers were presented (89 in the 2005, 85 in the 2006 and 99 in 2007) in the following areas:

- 51 posters
- 36 application and development
- 31 technical solutions
- 22 coder corners
- 18 coding solutions (2006 and 2007 stream)
- 17 Statistics & Pharmacokinetics
- 17 Tutorials
- 13 CDISC and XML (2005 stream)
- 13 Data Management
- 11 CDISC and Regulatory (2007 stream)
- 10 Professional Development & Management (2005 and 2006 stream)
- 10 Regulatory Compliance, Electronic Submission & Validation (2005 and 2007 stream)
- 7 SAS Starters (2005 and 2006 stream)
- 5 Management (2007 stream)
- 4 Industry Starters (2007 stream)
- 4 Professional Development and Training (2007 stream)
- 2 Microsoft Tool (2007 stream)
- 2 Oracle Clinical (2007 stream)

The ultimate objective of this sort of 'systematic review' is to make a summary of the current contribution of PhUSE to the Pharmaceutical Software User Community.

INTRODUCTION

Someone may argue: "why waste time doing this review?". We can answer by first saying that since last year we enjoyed reviewing approximately one hundred web sites with useful SAS® contents[1], this year we wanted to repeat this story and therefore we performed a similar review by using another resource channel.

PhUSE is a resource for everybody, not just for those attending the conferences, but also for those accessing the PhUSE by surfing the net. Further, people attending the conferences may have missed what was a potentially useful speech and perhaps didn't have time later to review the articles presented. Therefore, we wanted to provide a useful service to everyone by highlighting, based on our experience, what has emerged from the PhUSE conferences so far. Also, because of our love for playing with tables and figures, we have calculated some summary statistics on who (country, pharma vs CRO) and what has been presented so far, whilst trying to identify something that has yet to be covered.

MATERIAL AND METHODS

Papers presented at the first (2005) and second (2006) and abstracts from the third (2007) edition of PhUSE user-group meetings were reviewed and the following information collected:

- country of presenters;

- type of organisation: Pharmaceutical company, CRO, Consultancy Companies (e.g. software or statistics only), Academic, Regulatory agency;
- keywords describing papers contents.

RESULTS

Overall 273 presentations were presented at the three PhUSE meetings, including the current 2007 editions, for which the analysis was based on abstracts. Nine presentations in the poster sessions have been removed since they had already been presented elsewhere (oral). Three presentations were excluded from the analysis because no information was available (missing papers on the PhUSE / Lex Jansen web site[2]). Overall 261 papers were reviewed, 162 from the 2005/2006 conferences (full papers or slides review) and 99 from the 2007 conference (abstract review).

A REVIEW OF THE WORKS PRESENTED

Table 1 reports the distribution of the characteristics. Papers were equally divided between Pharmaceutical and CROs/Consultancy Companies (33% for pharmaceutical companies vs 28% for CRO and 29% for consultancy companies). The majority of the presentation came from UK based companies (43%), followed by Switzerland (12%) and Germany (8%); this is easily explained by the language and the European geographical location of companies involved in the Pharmaceutical sector. The majority of presentations discussed solutions/issues related to the SAS System (197, 76%), although there appears to be a decreasing trend in the number of such presentations (around 65% in 2007, compared to 83% In 2006 and 81% in 2005), however this data should be confirmed following a complete review of the presentations that will be presented this year. There has also been a relevant number of presentations (46, 18%) discussing methodological issues (professional development, statistical methods, etc) not related to any specific software. Many of the presentations discussed in-house solutions (N=33), such as applications for either producing TLG - Tables, Listing and Graphs (N=27) or documenting SAS programs (N=11), confirming that statistical analysing and reporting is where the SAS System is mainly used in the Pharmaceutical sector.

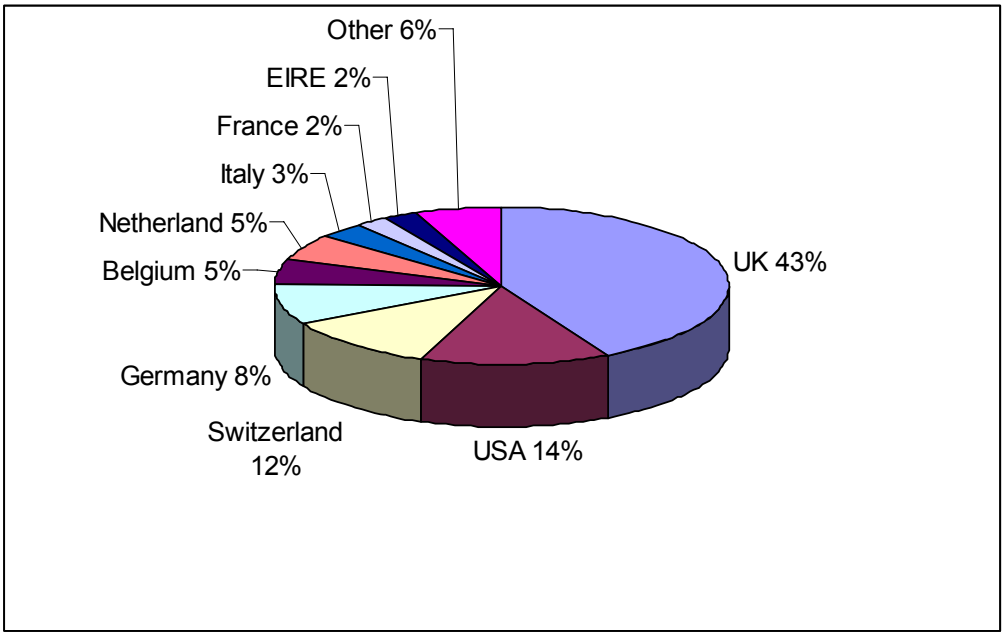

Figure 1: Country Distribution of Authors of Papers Presented

SAS UTILISATION

As previously highlighted, the majority of the presentations discussed the issues/use of SAS, which confirms that the SAS System is predominant in our sector, at least for biometric activities (statistical analysis and programming). However SAS 9 details, such as new features, tips, etc., were provided in only 9 presentations.

Apart from SAS/BASE®, which is of course used in all SAS applications, SAS/GRAPH® (18 citations), SAS/AF® (11 citations), SAS/ETL® (9 citations) and SAS/STAT® (9 citations), were the main modules cited in the presentations/solution presented.

ODS techniques and their use were described in 31 presentations, confirming the great success of this late 1990's SAS revolution. Our favourite SAS tool, the macro facilities, despite the emerging solutions integrated in SAS continue to be highly used in the SAS community, with 36 papers discussing both macro application (routines) and techniques.

WHERE DID WE FIND THE MOST INTERESTING TIPS?

ODS RESOURCES

As shown in table 1 'ODS' is one of main represented keywords used to define the papers presented so far according to our review; it is probably the most important 'revolution' of SAS since the SAS 6.12 was dismissed. Therefore, as the ODS language is also not always easy to understand, we found the papers discussing ODS characteristics, tips and secrets, the most interesting.

We would like to cite the paper presented by Steve Proust in 2005[3] where he described his experience step by step in moving from standard ASCII file output to RTF, whilst the paper presented by Leroy Bessler[4] contains good tips for using ODS to PDF. Also papers from Rob Walls[5], John Kirkpatrick[6] and David Shannon[7] were very useful and well exposed.

PROGRAMMING TECHNIQUES

Presentations from Ian Amaranayake[8] and Dante diTommaso together with Benjamin Szilagyi[9], contain good references for new functions in SAS 9 and useful and sometime hidden tips of the SAS System. Moreover, a good overview of what new in SAS 9 latest version for Clinical Programmers is the presentation from SAS UK representative Dave Smith[10].

APPLICATION DEVELOPMENT

Everyone should have a copy of the work presented by Jim Groeneveld[11], a comprehensive review of GVP (Good Validation Practice) in developing SAS macros. Also presentations from Chris Olinger[12] and Raymond Ebben[13] were interesting in reviewing possible techniques for web publishing, including pharmaceutical portals, with SAS instrument together with other standard technologies, such as XML, Java.

OTHER USEFUL PRESENTATION

We knew solution and tips of Phil Holland through the web before PhUSE and therefore we couldn't miss his presentations; the one in Heidelberg in 2005[14] was the most interesting discussing possible interface from SAS to other software, such as R to take advance of its graphical facilities.

An other example of integration of SAS with other software, is the work presented by Joel Hoffman and Michael O'Connel, where we personally also had the opportunity to see a bit of the potentiality of S-Plus[15].

Last year when we back from Dublin (PhUSE 2006) the first action we made as soon as the papers were available in the Lex Jansen website, was to send the papers of Malachy Foley[16] to colleagues and friends: everyone working at least 4 hours a day with computers, must read this paper to know the risks of bad attitude especially in using mouse and keyboard and follow Malachy suggestions.

PLAYING A BIT WITH THE DATA

Since our background is in statistics and programming and due to the availability of a lot data, we have tried to perform an analysis within SAS/STAT tools to look for specific patterns describing the attitude in presenting papers at PhUSE between the Pharmaceutical Industry and the CROs/Consultancy Companies presenters.

We considered the Logistic Regression Model utilizing the backward selection procedure as the most appropriate to be applied. The dependent variable was 'Pharmaceutical user (1=Pharmaceutical/Biotech User, 0=CRO/Consulting User)' whereas the independent factors were the keywords used to describe papers contents. The model selected the following keywords:

- in-house, with a positive association to Pharmaceutical users; in-house was a keyword used when the paper was about, or cited, an in-house solution (e.g an application for output reporting);
- stat, with a positive association to CRO/Consultant users; stat was a keyword used when the paper was about a statistical method or an application of a specific statistical methods;
- routine, with a positive association to Pharmaceutical users; routine was a keyword used when the paper was discussing a solution by means of a SAS macro routine;
- pk, with a positive association to Pharmaceutical users; pk was a keyword used when the papers discussed issues related to the management (and analysis) of PK/PD data.

The above results suggest that 4-keywords ('in-house', 'stat', 'routine' and 'pk') were sufficient to model the different attitudes in presenting papers between the pharmaceutical sector and CRO industry. Further 'true' pattern analyses would need to be performed in order to fully appreciate the contribution of each of these factors to the relevant industry.

MISSING OR FEARLY TREATED AREA

So far the PhUSE goal of creating a place where European software users from the pharmaceutical industry can meet and share experiences has been satisfied: the numbers are clear, about 300 participants have attended the first two conferences and a similar attendance is expected for this year conference; many technical issues have been discussed and good 'first-time' tutorials have been presented. However we want to point out three main issues resulting from the first two user-group meetings:

- the strong dependency on SAS (75% of papers presented): this is explained in part by the fact SAS is still the format for data transmittal to the health authorities; there is also a lack in the use and availability of open source software;
- although the aim of the user-group is strictly technical, we think that there should be more space for methodological papers discussing issues more related to the data rather than the software used;
- although the user-group is for Pharmaceutical software users, we expected to see more participants from non-profit organisations (eg. national research councils). We wish that these 'parties' be more involved in the

future so that they might share their valuable and sometimes 'un-biased' input.

POSSIBLE IMPROVEMENT OF THE PHUSE INITITIATIVE

Although we understand that it is difficult to manage such as huge user-group, whilst performing our daily business activities, we think that the user-group should be more motivated in sharing idea, tips, etc., during the year before they meet at the conference. An idea would be to improve the official platform (www.phuse.info) by reporting the user-group initiatives and adding useful sections for sharing tips, and requesting help/suggestions (e.g. a blog).

PHUSE VS OTHER SIMILAR USERGROUP

PharmaSUG can be considered the 'mother' of all pharmaceutical user-group around the world. It was founded about 15 years ago (march 1989 in Bethesda, Maryland) and in the recent conferences it had an average of about 600 attendees (677 attendees in 2006 in Denver) with about 130 presentations.

With respect to PhUSE, PharmaSUG is fully dedicated to SAS users. We did not have the time to perform a qualitative review of the papers presented in order to make some sort of comparison with PhUSE experience; however, based on a quick review of title presented at the last conferences, we found a lot of technical papers as in PhUSE mainly dedicated to ODS, CDISC, MACRO. There were also several contributions from University and others Academics Organisations and there was also a dedicated section to the Public Health Research (in the recent editions, in 2005, 2006 and 2007).

Characteristic (N=261)	**N**	**%**
Type		
Pharmaceutical	96	36.8
CRO / Consultancy	163	62.4
SAS	14	5.4
Other (Academic, Regulatory Agencies, Other SAS Vendors)	14	5.4
Application Used/Involved		
SAS	197	75.5
S+ / R	7	2.7
VBA	7	2.7
ClinTrial / Oracle Clinical	5	1.9
MS.NET	3	1.1
Other	19	7.3
SAS Main Modules Used		
STAT	18	6.9
AF	11	4.2
ETL	9	3.4
GRAPH	9	3.4
Main Keywords Identified		
CDISC	33	12.6
In-house developed solutions	33	12.6
ODS	31	11.9
Programming Techniques	31	11.9
Macro	19	7.3
Computer System Validation	14	5.4
PK	11	4.2

Table 1: Characteristics of Papers Presented

CONCLUSIONS

For the third year running, the PhUSE conference. 2007 in Lisbon will provide a central forum for pharmaceutical software users throughout Europe to share their experiences, trade their knowledge and liaise with peers. Given the distribution of the pharmaceutical industry and the location of PhUSE, it is perhaps not surprising that most of the presentations given over the last 2 years have come from users situated in the UK, Switzerland and Germany (users from US location were mainly from SAS Institute and other in representation of CDISC). That presentation discussing specific issues relating to SAS have been the most numerous is also unremarkable given its history with the regulatory authorities. However, in this regard there may be a trend towards other software. In part, it might also be due to the desire for ever increasing complex clinical trial designs that require more specialized statistical software. The topics for discussion have also been varied and will no doubt continue to diversify into more intricate corners of pharmaceutical software programming.

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